news along the pike

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PIKE'S CORNERS . . .

Dr. Woodcock provides highlights of her detail

Implementing quality systems, collaboration with NIH top list

BY JANET WOODCOCK, M.D.

Over the past few months, I've been on detail to the Office of the Commissioner, working on special projects. My plan was to get these well underway and return to CDER in late April. I've been enjoying working with many of you to get these initiatives started.

As you know, I have been asked to extend my detail in order to serve as the acting deputy commissioner for operations. I will continue to work on the various initiatives, and I will also be charged with managing a number of day-to-day program operations. The length of this detail is open-ended, but I will try to keep you well informed of any plans for the future as they develop.

A number of the initiatives I have been working on, such as quality systems and better collaboration with the National Institutes of Health, will have a long-lasting and far-reaching impact on the way we do our work.

Quality systems

We are starting down a long road to quality systems to bring order and clarity to the Agency's work. We already have many quality systems and subsystems in place, so we will build on those.

The basic concepts underlying quality systems are quite simple: say what you do, do what you say, prove it and improve it. We have been working on developing common nomenclature and a jargon-free framework to help you

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Office of Testing & Research first to move to White Oak

BY PATRICK E. CLARKE

The Office of Testing and Research is the first CDER group to make the long-awaited FDA consolidation move to the White Oak facilities. While there were some glitches, overall the move has been very positive for the office, according to **John M. Strong, Ph.D.,** deputy director of the Laboratory of Clinical Pharmacology.

"The CDER laboratory component has been trying to consolidate since I started with the Center in 1990," Dr. Strong said. "We've had laboratories located in Gaithersburg, D.C. and Laurel. Now, we are consolidated for the first time since I've been here."

He regards the consolidation of divisions as the biggest asset of the move (click here to view photographs). "Now, we have direct communication between all of our investigators, which provides the opportunity for more collaboration and can be more intellectually stimulating," Dr. Strong said.

In addition to the Laboratory of Clinical Pharmacology, the 48-member office includes the Divisions Applied Pharmacology Research,

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FDA issues draft guidances on direct-to-consumer advertising

FDA issued three draft guidance documents designed to improve communications to consumers and health care practitioners about health conditions and medical products on Feb. 4. The guidances are the result of FDA research and policy development, and were influenced by public participation at an open meeting on consumer-directed advertising held by FDA in September (November *Pike).*

The draft guidances provide advice on:

- Alternatives to the lengthy, detailed and technically written "brief summary" of risk information for consumer-directed print advertisements for prescription drugs, with the goal of increasing consumer understanding of the key risks of the product.
- The use of disease awareness communications, which are designed to educate patients or health care practitioners about particular diseases or health conditions and do not promote a particular medical product, with the goal of getting more patients to

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Dr. Woodcock's top projects: quality systems, NIH collaboration

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implement quality systems in your work.

The Senior Management Team and I will be having a strategic planning retreat in preparation for the quality systems program that will have projects starting in the summer

Collaboration with NCI

We are exploring ways to facilitate interactions between FDA and NCI in the development and review of drugs and biologics to treat cancer.

As part of the FDA-NCI collaboration we will pull together all that's known about the use of imaging agents in oncology drug development and make that available to developers and reviewers. We have a large steering committee that will invite speakers and likely organize a workshop on imaging techniques. We are setting up three subcommittees to draft papers for publication in peer-reviewed journals on:

- Development of volumetric anatomical imaging for oncology—revision of RECIST (Response Evaluation Criteria in Solid Tumors).
- Validation of FDG-PET for oncologic drug development and as a surrogate endpoint for drug approvals.
- Pathway for accelerating molecular imaging including first-in-man studies in diagnosed cancer patients.

We are also working on clarifying various regulatory procedures.

NIH Roadmap

We are setting up other collaborations with the NIH on their Roadmap initiative. Achieving some of their objectives, especially in the clinical research area, will require partnership with FDA. The NIH Roadmap sets forth an ambitions vision for a more efficient and productive system of medical research. It focuses on the most compelling opportunities in three areas: new pathways to discovery, research teams of the future and re-engineering the clinical research enterprise. (More information is available at http://nihroadmap.nih.gov/.)

Good Manufacturing Practices

I will continue to chair the GMP initiative. In addition to moving this broad initiative forward, we also are working on a multicenter draft guidance that will help laboratory- and small-scale drug developers comply with our cGMP regulations. This will help researchers, who only make a batch or two of a drug for investigational use in humans, understand what is required to reproducibly make a good quality investigational product. The cGMP regulations were writen primarily with large-scale production and postmarketing manufacturing operations in mind.

Follow-on biologics

We are writing a scientific guidance that describes the principles of determining the similarity of protein molecules. CDER regulates proteins of many kinds under the Food Drug and Cosmetic Act and also the Public Health Service Act.

Cross-Agency guidances

We want to expedite publication of guidances on pharmacogenomics and drug-eluting coronary artery stents. The comment period on the pharmacogenomics guidance closed on Feb. 2, and we are evaluating the comments. We have set up a working group to begin drafting the drug-eluting stent guidance.

Center Director Janet Woodcock is currently on detail as the deputy FDA commissioner for operations.

FDA draft guidances encourage more consumer-friendly DTC advertising

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discuss under-treated conditions with their doctor.

- Compliance with federal risk disclosure rules for consumer-directed broadcast advertising for certain medical devices.

Brief summary

Typically, manufacturers fulfill the brief summary requirement by including the complete risk-related sections of the FDA-approved professional labeling in the ad in small type. Risk information presented in this manner is designed to satisfy applicable regulations but is not user friendly.

While this risk information is technically in compliance in that it contains important information on benefits and risks, it does not convey key information effectively to many consumers. This draft guidance is designed to encourage manufacturers to deliver more user-friendly information to the public so that they can be better-informed partners in their own health care.

Help-seeking, disease awareness ads

This draft guidance clarifies the criteria that FDA will use to distinguish manufacturer communications that provide information about the importance of recognizing that certain signs and symptoms may be evidence of a treatable disease from manufacturer promotional messages for particular treatments for a disease. The latter, but not the former, are subject to FDA regulation as advertising or promotional labeling.

FDA hopes that, by providing clarity, it will encourage manufacturers to provide more educational messages to the public. This draft guidance includes clarifications on "bookend" advertisements in print or broadcast formats. These advertisements or labeling pieces consist of two parts:

- First is either a "reminder" piece, which includes the name of a drug or device but makes no safety or effectiveness claims or a full product promotional piece.
- Second is a disease awareness message, which encourages consumers to seek health care practitioner assistance or practitioners to provide such assistance in identifying and treating a particular health condition but does not mention any product by name.

Disease awareness and reminder communications alone would not be subject to FDA rules for requiring risk disclosure. But, when reminder and disease awareness or full product and disease awareness pieces that use similar themes, story lines or other presentation elements are taken together, FDA is concerned that they can be understood as product claim pieces and the Agency will regulate them as such.

The draft guidance provides advice to manufacturers on the criteria FDA uses in determining whether such disease awareness messages are subject to regulation as advertisement or labeling. The criteria, in brief, are whether the two components are perceptually distinct and whether they are separated in space or time.